UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

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ROBERT JONES and KRISTA JONES,

Plaintiffs,

Civil Action No.: 08 CV 2060 (JAP)

-against-

SYNTHES USA SALES, LLC, SYNTHES USA PRODUCTS, LLC, JOHN DOES 1-5, and ABC CORP. 1-5,

Defendants.

DOCUMENT ELECTRONICALLY FILED

Motion Date: May 3, 2010

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REPLY BRIEF IN FURTHER SUPPORT OF DEFENDANTS SYNTHES USA SALES, LLC AND SYNTHES USA PRODUCTS, LLC'S MOTION FOR SUMMARY JUDGMENT AND TO PRECLUDE THE TESTIMONY OF PLAINTIFF'S EXPERT WARREN LIEBERMAN

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I. PLAINTIFF'S OPPOSITION DOES NOT RAISE A TRIABLE QUESTION OF FACT ON FAILURE TO WARN.

A. New Jersey applies the learned intermediary doctrine to medical device cases.

Plaintiff argues that the learned intermediary doctrine does not apply to medical device cases in New Jersey. Plt. Opp., p. 6. While the New Jersey Supreme Court has not addressed the issue, in *Spychala v. G.D. Searle & Co.*, 705 F.Supp. 1024 (D. New Jersey 1988), the United States District Court for the District of New Jersey, interpreting New Jersey law, applied the doctrine in a product liability case involving a medical device – an intrauterine contraceptive device. Similar to the ATB, an intrauterine device can only be dispensed with a prescription and can only be implanted in a patient by a physician. *Id*. at 1026.

Here, plaintiff does not dispute that the Synthes Anterior Tension Band ("ATB") system is a prescription medical device. See Plt's Response to Synthes' Statement of Material Facts, No. 1. As such, it is only available when prescribed by a duly licensed physician and, given its purpose, would only be implanted by a trained spinal surgeon. Plaintiff has not cited a single case where a New Jersey court rejected the application of the learned intermediary doctrine in the prescription medical device context. There is no reason to believe that a New Jersey court would not follow the reasoning of *Spychala*, supra, and also jurisdictions throughout the country in applying the learned intermediary doctrine

to medical devices such as the ATB. *See Baker v. Danek Medical*, 35 F.Supp.2d 875, 881 (N.D.Fla.1998)(Florida law); *see Ellis v. C.R. Bard*, 311 F.3d 1272, 1280 (11th Cir. 2002)(Georgia law); *see Adams v. Synthes Spine Co.*, 298 F.3d 1114, 1117 (9th Cir.2002)(Washington law); *Willett v. Baxter Int'l, Inc.*, 929 F.2d 1094, 1098 (5th Cir. 1991)(Louisiana law); *Porterfield v. Ethicon, Inc.*, 183 F.3d 464, 468 (5th Cir.1999)(Texas law); *Allen v. G.D. Searle & Co.*, 708 F.Supp. 1142, 1147-48 (D.Or.1989)(Oregon law); *Hill v. Searle Laboratories*, 686 F.Supp. 720, 725 (E.D.Ark.1988)(Arkansas law); *Lacy v. G.D. Searle & Co.*, 1988 WL 67825 (Delaware law); *McKee v. Moore*, 648 P.2d 21, 23-25 (Okla.1982) (Oklahoma law); *Perfetti v. McGhan Medical*, 99 N.M. 645, 662 P.2d 646, 650 (N.M.App.)(New Mexico law).

B. Plaintiff has not set forth a prima facie case on failure to warn.

Plaintiff argues that the Synthes warnings are inadequate because, counsel alleges, the insert does not contain adequate information on the dangers and safe use of the product. Plt. Opp., p. 7. More specifically, counsel, rather than his expert, argues that Synthes should have set forth a possible lifespan for the device once implanted in a patient and should have provided an estimated time span for a spinal fusion to occur. Id.

Plaintiff's argument lacks merit. It is not possible to provide a "possible" lifespan for the device or an estimated time span for spinal fusion to occur because

the stresses encountered by the ATB after implantation differ for each patient and because whether a particular patient will achieve fusion or not, and if so, how long it will take varies by patient. See Zardiackas Aff. ¶ 6 at Ex. I. Second, the warnings provided with the ATB clearly advise of the risks of device breakage ***at any time*** should the device be subjected to sufficient stresses or from a delay or lack of fusion. See Ex. A attached[1]. The Synthes Package Insert, which accompanies each shipment of Synthes product, specifically states: "If there is delayed union or nonunion of bone in the presence of weight bearing or load bearing, the implant could eventually break due to metal fatigue" and "[i]t is important to note that these implants may break *at any time* if they are subjected to sufficient stresses." Id. Plaintiff does not offer any alternative warnings which he contends would have better conveyed the risks and benefits of the ATB.

Plaintiff's opposition is deficient as it does not include the affidavit of a physician to support plaintiff's criticisms of the Package Insert. *See Grobelny v. Baxter Healthcare Corp.*, 2008 WL 2186417 (D. New Jersey 2008)(finding in a pharmaceutical case that the testimony of a physician would be necessary for the trier of fact to understand whether the warning was adequate because case involved a complex product with a complicated warning insert.); *see also Laspesa v. Arrow*

[1] Annexed hereto as Ex. A is the 2003 Synthes Package Insert which was in effect during plaintiff's July 2005 surgery. Said insert was disclosed during the fact discovery period at SYNTHES 000204 and was marked as Exhibit 5 at the deposition of plaintiff's expert Warren Lieberman on August 20, 2009. A prior version of the insert was inadvertently included as Ex. L to Synthes' moving papers.

International Inc., 2009 WL 5217030 (D. Mass. 2009)(expert testimony was required as to the adequacy of warnings concerning a catheter.) Given plaintiff's failure to retain a medical expert, he has no basis to counter the testimony of plaintiff's operating surgeon, Mark Levine, M.D., that he was well aware of the risk of device breakage from lack of bony fusion from his residency training. Levine Dep., p. 21-22 at Ex. R. He also has no basis to counter the affidavit of Dr. Joel Spielman, a spinal surgeon retained by Synthes, who opined that the Synthes Package Insert "contain[s] appropriate information as to the risks and benefits of the Anterior Tension Band System." Spielman July 8, 2009 Rpt, p. 3, Ex. H.

Notably, even plaintiff's own expert, Warren Lieberman, testified that he had no criticism of the Package Insert and he "did not find anything in there that was contrary to his opinions." Lieberman Dep., p. 108-109 at Ex. S. Based on the foregoing, plaintiff's failure to warn claims against Synthes must be dismissed.

II. PLAINTIFF HAS NOT MET HIS BURDEN OF SHOWING EVIDENCE OF PRODUCT DEFECT.

In order to prove product defect under the New Jersey Product Liability Act, it is plaintiff's burden to prove the existence of a reasonable alternative design that is safe, feasible and retains the function of the original device. *See Quincy Mutual Fire Insurance Company v. Scripto USA*, 573 F.Supp.2d 875, 879 (D. New Jersey 2009).

Here, plaintiff cannot meet this burden because his expert, Mr. Lieberman, who is not a licensed engineer in any state, lacks experience in the field of fusion surgery, biomaterials and internal fixation devices. Lieberman Dep., p. 12, Ex. S. Further, Mr. Lieberman's proposed alternative manufacturing methods for the cancellous bone screws used in the ATB exist only in his mind, have not even been reduced to an engineering drawing or manufacturing flow chart and have never been tested or peer-reviewed for safety, form, fit or function in humans.

For example, as to shot peening, plaintiff submits the ipse dixit of his expert that "shot peening would not have any deforming impact upon the screw beyond a millionth of an inch and would not interfere with the ability of the screw to function." Plt. Opp., p. 13. Plaintiff admitted, however, in Response to Synthes Statement of Material Facts ¶ 50, that Mr. Lieberman cannot identify how the shot peening process would affect a surgical screw such as those that failed in plaintiff because he has never shot peened a surgical screw. He also admitted that "Mr. Lieberman has not done any testing to determine whether strengthening the cancellous screws such as those used in Mr. Jones' [spine] would have impeded bone growth and fusion." See Response to Synthes Statement of Material Facts ¶ 48. The same deficiencies exist with respect to plaintiff's alternative design method called gray anodization. As opined by Dr. Zardiackas and admitted by plaintiff, gray anodization would increase the lubricity of the screw. Dr.

Zardiackas opines that such increased lubricity could, in fact, detrimentally affect the screw's ability to maintain purchase (stay within the bone), a critical function of the screw. Since it is plaintiff's burden to prove a feasible alternative design, his argument that Synthes has not proven that increased lubricity would negatively affect the function of the screw lacks merit. Dr. Zardiackas also opines that gray anodization would impart a gray color to all of Synthes screws and interfere with the function of the ATB screws' color coding scheme which is used to avoid sizing errors during surgery. Plaintiff arbitrarily disregards this function claiming that it is absurd for Synthes to be concerned about sizing errors. Plt. Opp., p. 14. While plaintiff claims that Synthes with "only a minimum of effort, could develop an alternative method of categorizing its parts," he suggests no such alternative method.

As a final alternative manufacturing/design method, Mr. Lieberman suggests that Synthes should have used dye penetrants as part of its inspection process to look for surface flaws in the material it uses to manufacture the screws used in the ATB. Mr. Lieberman testified, however, that he could not identify any specific flaw in the manufacture of the screws in this case. Lieberman Dep., p. 126 at Ex. S. Moreover, as with plaintiff's other alternative design, plaintiff offers no reliable support for the application of dye penetrant inspection with implants intended for use in humans. His claimed experience working with this method while

manufacturing helicopter parts does not count. He testified that he is not aware that dye penetrant inspection has ever been used for surgical screws. Lieberman Dep., p. 223. He is not aware of any company that makes screws for use in spinal fusion that performs dye penetrant inspection of the screws. Lieberman Dep., p. 223, 229. He has performed no analysis as to whether it is feasible or safe to use dye penetrants on a screw meant for implantation in the human body. Lieberman Dep., p. 238 at Ex. S. He testified that he has not done any testing to determine whether you can dye penetrant test the ATB screws and then completely remove the chemical residue from the screws prior to implantation. Lieberman Dep., p 268. He is not aware whether the solvents used in dye penetrant testing are biocompatible with humans. Lieberman Dep., p. 271-272. He has not analyzed whether utilizing this method on every screw manufactured by Synthes is feasible from a cost perspective. Lieberman Dep., p. 238. Since plaintiff has the burden of proof, he cannot prove the existence of a reasonably safe alternative design without such evidence.

It is pure speculation by plaintiff's counsel that plaintiff's surgical outcome would have been different, and he would have achieved solid fusion, had Synthes used the alternative manufacturing methods suggested by Mr. Lieberman. There are many medical reasons, unrelated to device breakage, why fusion may not occur and a re-operation may be necessary including underlying medical conditions,

patient activity, obesity, diabetes, cigarette smoking and lack of compliance with post-surgical instructions. See Spielman Aff. ¶ 10 at Ex. H. While plaintiff's counsel may surmise that had the screw not broken when it did, that fusion would have occurred, such supposition is not reliable evidence. No one can predict the future. Since plaintiff provides no support, expert or otherwise, for this claim, summary judgment should be granted in favor of Synthes.

III. PLAINTIFF'S CRITICISM OF SYNTHES' TESTING OF THE ATB LACKS SUPPORT.

As a catchall theory, plaintiff criticizes the manner in which Synthes tested the ATB prior to FDA clearance. He argues that Synthes' testing failed to account for all of the various stresses that the screws would experience in a human body. He also argues that Synthes is at fault for testing the ATB system (plate and screws) as a whole rather than testing each component part individually.

Plaintiff's criticisms are without merit. The ATB is a system comprised of a plate and screws. The individual component parts are never used in isolation. The system itself is tested in accordance with industry and FDA standards. Since the ATB is sold and implanted in patients as a system, plaintiff provides no proof as to what useful information would be gained by testing the component parts in isolation. He also fails to cite a single peer reviewed study or other surgical implant manufacturer that tests in this manner.

While plaintiff argues that Synthes should have performed additional tests of fatigue life, he fails to provide protocols for these tests or describe what purpose these additional tests would serve. As set forth in Synthes' moving papers, since the stresses placed on an internal fixation device vary for each patient, the industry has never developed a test that can provide a scientifically based prediction as to an expected life span for an internal fixation device. See Zardiackas Aff. ¶ 6 at Ex. I. Unlike airplane wings, automobile suspensions or bridges, where tests of fatigue life are possible because the stresses are predictable, there have been no tests developed by ASTM International or any other agency for determining the in vivo fatigue life of orthopedic fixation implants. Id.

Moreover, Synthes tested the ATB in accordance with industry and FDA standards by running both a static axial test and a dynamic axial compression/tension fatigue test to 10,000,000 cycles. See ATB test results at Ex. O- SYNTH001738 – SYNTH 1742; Deposition of Benjamin Barrall, p. 60-62 at Ex. T. Plaintiff's expert testified that the testing performed by Synthes was approved by the FDA as acceptable for the ATB. Lieberman Dep., p. 149 at Ex. S. He further testified that said testing allowed Synthes to compare its product with those of other manufacturers that underwent similar testing. Id. at p. 149. He conceded that testing to 10,000,000 is standard and had no criticism of same. Id. at p. 151.

Since neither plaintiff nor his expert have run any tests (either industry standard tests or their own proposed tests) on an exemplar ATB, it is rank speculation on plaintiff's part that the ATB would not have passed whatever additional tests plaintiff argues Synthes should have performed. Given the foregoing, plaintiff's criticisms of Synthes' testing does not provide a basis to deny summary judgment.

IV. PLAINTIFF HAS NO PROOF OF MEDICAL CAUSATION.

Plaintiff cannot prove medical causation. He has not provided an affidavit from a physician supporting his claims that the breakage of the ATB screws caused his failure to achieve fusion, necessitated his second operation or that his current complaints are related to the breakage of the ATB screws. He concedes that his sole expert, Mr. Lieberman, is not being proffered as an expert with regard to any medical issue. Plt. Opp., p. 18. Plaintiff tries to circumvent the need for expert medical causation by relying solely on his own testimony that he developed back pain after feeling a "pop" in his back which he attributes to the breakage of an ATB screw. He argues that when an injury immediately follows a traumatic event and is clearly related to the event, a party can establish causation despite the lack of expert medical testimony e.g. a broken ankle following a trip and fall.

Given plaintiff's long history of multi-level disc disease and the complex nature of the spinal fusion surgery performed by Dr. Marc Levine (which was only

meant to treat the L5-S1 level of his spine), this is not a simple case as suggested by plaintiff where a causal connection between plaintiff's claim of injury and product can be established without expert testimony. There is also no medical support for plaintiff's claim that the pain he claimed to have experienced after feeling the "pop" in his back was caused by the breakage of the ATB screws. Notably, plaintiff testified that Dr. Levine told him that the "pop" he felt was likely related to scar tissue. Jones Dep., p. 194 at Ex. Q.

Plaintiff's expert testified that it was out of his area of expertise as to whether the "pop" plaintiff allegedly felt was related to a fracture of the screw rather than the release of scar tissue or some other process. Lieberman Dep., p. 50 at Ex. S. He further testified that, given the size of the ATB screw, a person might not even hear it break. Lieberman Dep., p. 51-52 at Ex. S.

As to plaintiff's post-operative complaints, Dr. Levine testified that they are unrelated to plaintiff's current complaints of pain. He testified "as far as the hardware in his spine, the hardware was nowhere in the vicinity of the nerves that would go down the left lower extremity to cause those symptoms." Levine Dep., p. 79 at Ex. R. Dr. Levine also testified that he specifically informed plaintiff that the findings of disc disease at other levels of his spine "could cause residual pain, even despite surgery at the L5-S1 level." Levine Dep., p. 58. There is therefore no medical support in the record for plaintiff's position.

Plaintiff's timeline is also wrong. The medical records show that he reported increased back symptoms on multiple occasions even before he allegedly heard the "pop" which he attributes to the breakage of the Synthes ATB screw. On April 18, 2006, plaintiff reported to Dr. Levine that he "had the onset of back pain after bending over with numbness and tingling going down his legs." SYNTH000238 at Ex. P. An x-ray taken that day showed "the instrumentation to be in place…" Id. Thus, the contemporaneous medical records do not support plaintiff's timeline of being pain-free prior to feeling the "pop."

Finally, plaintiff fails to offer any expert medical proof to support his argument that the second surgery resulted from the breakage of the Synthes ATB screw rather than his failure to achieve fusion. Dr. Levine's records do not support his position. A May 18, 2006 note from Dr. Levine, following a CT scan of the lumbar spine, states: "based on the broken hardware, we have to assume that the fusion is not yet solid. For this reason, I am recommending a posterior stabilization procedure…" SYNTH000236 at Ex. P. Thus, contrary to what plaintiff argues, Dr. Levine felt the broken screw was a sign of the fusion not being solid rather than a cause of plaintiff not achieving fusion.

Since plaintiff has failed to retain an expert who can address medical causation, he cannot contest the evidence that 1) his failure to fuse caused breakage of the ATB screws; 2) that the failure to fuse necessitated revision surgery; 3) that

he had pre-existing disc disease at other levels of his spine that were not treated during his surgery; 4) that his current complaints are not related to the breakage of the ATB screws and; 5) that the limited goals of the surgery were achieved. Accordingly, he cannot prove causation, an essential element under the NJPLA, thus requiring summary judgment in favor of Synthes.

V. MR. LIEBERMAN SHOULD BE PRECLUDED FROM TESTIFYING.

Plaintiff argues that Mr. Lieberman should be permitted to testify because he is qualified to offer an opinion regarding the strength of a metal screw given his experience working as a metallurgical engineer. Plt. Opp., p. 21. Plaintiff argues that Synthes attempts to confuse the issue by suggesting that expertise in the areas of fusion surgery or biomaterials is necessary to understand the screw issue. Id. Plaintiff suggests that since Synthes 30(b)(6) designee, Benjamin Barrall, is not a physician that Mr. Lieberman does not need expertise in this area either.

Plaintiff's argument misses the point. It is plaintiff's burden, as the proponent of the expert testimony, to establish the admissibility of Mr. Lieberman's opinion by a preponderance of the evidence. *See In Re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 744 (3d Cir. 1994). Since plaintiff has not filed a *Daubert* motion challenging Mr. Barrall, his background is irrelevant to Synthes' motion. Moreover, unlike Mr. Lieberman, Mr. Barrall has over six years of experience working for a medical device company. Unlike Mr. Lieberman, his

employment has provided him with experience and training in the manufacture and design of internal fixation devices.

Mr. Lieberman's experience working in a Boeing factory that made helicopter parts is vastly different from the knowledge and experience necessary to design internal fixation devices meant for human implantation. For Mr. Lieberman's testimony to be of assistance to a jury, as required under Rule 702, he needs experience in, not only metals, but also internal fixation devices, fusion surgery and biomaterials. This is especially true in this case where plaintiff has failed to retain a medical expert to supplement the opinions of Mr. Lieberman.

In the medical device context, numerous courts have excluded expert testimony based on an expert's lack of education, experience and qualifications in this specialized field of medicine. *See Muller v. Synthes Corp.*, 2001 WL 521390 (N.D.Ill. 2001); *see also Krueger v. Johnson and Johnson Professional, Inc.*, 2002 WL 34371190 (S.D. Iowa 2002). The same result should occur here.

As to methodology, Mr. Lieberman's proposed alternative manufacturing methods for the cancellous bone screws used in the ATB exist only in his mind, have not been reduced to an engineering drawing or manufacturing flow chart and have never been tested or peer-reviewed for implantation into human beings. As set forth in detail in Synthes' moving papers and in Section II above, his opinions are therefore unreliable and speculative. Since plaintiff has the burden of proof, he

cannot overcome the lack of testing and peer review by arguing that Synthes has not proven through its own testing that plaintiff's alternative design/inspection methods would not compromise safety, fit and function. It is plaintiff's, rather than Synthes', burden to show the existence of an alternative design that is safe, fit and practicable for the function intended. Plaintiff's failure to meet this burden warrants preclusion of Mr. Lieberman's opinions and summary judgment in Synthes' favor.

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PROOF OF MAILING AND CERTIFICATE OF SERVICE

DOCUMENT ELECTRONICALLY FILED

I, BARRY GERSTMAN, hereby certify and affirm that a true and correct copy of the attached REPLY BRIEF IN FURTHER SUPPORT OF DEFENDANTS SYNTHES USA SALES, LLC AND SYNTHES USA PRODUCTS, LLC'S MOTION FOR SUMMARY JUDGMENT AND TO PRECLUDE THE TESTIMONY OF PLAINTIFF'S EXPERT WARREN LIEBERMAN was served via regular mail and electronically on this 9th day of April, 2010, upon the following:

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